UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA ex rel. JAMES MARCHESE,

Plaintiff,

v.

CELL THERAPEUTICS, INC., et al.,

Defendants.

No. CV06-0168 MJP

ORDER GRANTING RELATOR 15% OF THE GOVERNMENT'S RECOVERY

This matter comes before the Court in a hearing on the issue of what percentage Relator James Marchese should receive of the proceeds resulting from the settlement of his claims against Cell Therapeutics, Inc ("CTI"). (See Dkt. Nos. 26, 29, 63.)

Findings of Fact

BACKGROUND

1. During the relevant time, CTI manufactured Arsenic Trioxide ("Trisenox") which was FDA approved for the treatment of acute promyelocytic leukemia ("APL"). Trisenox is not FDA approved for the treatment of any other form of cancer.

2. Under the FDCA (21 U.S.C. §§ 301-99), drug manufacturers are prohibited from marketing or promoting a drug for a use which has not been approved by the FDA (an "off-label use").

3. Physicians may prescribe an FDA approved drug for the treatment of diseases not included in the FDA approval as long as the use is considered within the reasonable practice of medicine under state law.

4. A specific off-label use for a drug is eligible for reimbursement by Medicare only if that indication is "medically accepted." 42 U.S.C. § 1395x(t)(2)(B). An off-label use is medically accepted if it is supported by a citation in any of three specified drug compendia published by third parties. 42 U.S.C. § 1395x(t)(2)(B)(ii)(I). Only two of those compendia existed during the relevant time: the United States Pharmacopoeia Drug Information ("USP-DI") and the American Hospital Formulary Service ("AHFS").

5. Any drug manufacturer who wishes to provide physicians with information concerning off-label uses of a drug must abide by the guidelines set out in 21 U.S.C. § 360aaa, et seq.

6. The Orphan Drug Act provides incentives to drug manufacturers to research treatment for diseases which affect a small portion of the population. 21 U.S.C. §§ 360aa-360dd.

7. A drug does not become medically accepted or FDA approved for a specific indication simply because it is granted orphan drug status.

8. When a doctor prescribes a drug for an off-label use, the drug is not eligible for Medicare reimbursement simply because the off-label indication is granted orphan drug status.

9. The USP-DI contains three volumes. Volume III contains a list of drugs which have obtained orphan drug status for a particular indication. This list is unrelated to the listing of medically accepted drug uses contained in Volume I of the USP-DI.

10. Many oncologists do not have direct access to the compendia and rely instead on a publication called the Compendia Based Drug Bulletin (the "ACCC Bulletin") in determining whether a drug is listed in the compendia as medically accepted for an indication. The ACCC Bulletin is published by the Association of Community Cancer Centers ("ACCC") and is provided to oncologists free of charge.

Trisenox's Listing in the ACCC Bulletin

11. Mr. Marchese was hired by CTI as an oncology account manager ("OAM") soon after CTI's drug Trisenox had been FDA approved for the treatment of APL. Mr. Marchese served as a sales representative along with eleven other OAMs and reported directly to Paul Sportelli.

12. Mr. Marchese was trained to promote Trisenox for the treatment of APL as well as for the treatment of the off-label indications multiple myeloma ("MM"), chronic myeloid leukemia ("CML"), and myelodysplastic syndrome ("MDS").

13. When Mr. Marchese was hired, CTI's marketing department was pursuing compendia approval for Trisenox indications MM, MDS and CML.

14. At the request of his direct supervisor, Peter Sportelli, Mr. Marchese took on a special project in addition to his sales representative responsibilities. Mr. Marchese prepared an analysis on how CTI could get Trisenox's off-label indications listed in the compendia so those indications could be reimbursable by Medicare.

15. Trisenox had been granted orphan drug designation for the MM, CML, and MDS indications. CTI hired Documedics, a consulting company specializing in drug reimbursement, to determine whether Trisenox's listing for its orphan drug designation in Volume III of the USP-DI was sufficient for Medicare reimbursement.

16. On September 19, 2001, Documedics Senior Research Analyst Andrea Dumat sent Mr. Marchese an email stating:

> As a follow-up to our telephone conversation here is the information I received on Trisenox "orphan drug status." 1. It has approved orphan drug status which means when it is listed in the Compendia it will show a 3 star listing. The 3 star indicates that Medicare carriers should reimburse for Trisenox under the orphan drug status. However, there is no guarantee that ALL Medicare carriers will reimburse for the drug. ...

(R. Ex. 6.)

17. Katie Schroeder, Executive Vice-President of Commercial Operations at CTI, and Mark Levonyak, the National Marketing Director of CTI, both advised Mr. Marchese that an off-label indication for a drug could be reimbursed based on its orphan drug designation. (See Marchese testimony, November 19, 2007, pp. 64-65.)

18. After receiving confirmation from Documedics that orphan drug status was sufficient for reimbursement, Mr. Marchese contacted Don Jewler at the ACCC. Mr. Marchese and Peter Sportelli met with Mr. Jewler to discuss publication of Trisenox in the ACCC Bulletin with an indication that Trisenox had been granted orphan drug status for its MM, MDS and CML indications. After the meeting, Mr. Marchese sent Mr. Jewler copies of the FDA letters granting Trisenox orphan drug status for MM, CML, and MDS.

19. On September 20, 2001, Don Jewler sent a letter to Mr. Marchese which included a "grant proposal" requesting that CTI pay ACCC a grant of $10,000/year and, in return, CTI would receive 3,000 copies of ACCC's Bulletin each quarter and ACCC would place a CTI advertisement on its website. (U.S. Ex. 2.) The stated objective of this grant proposal was "to raise awareness among oncology health care professionals about [CTI] and Trisenox (including its orphan drug designation for the treatment of MDS, multiple myeloma, and APL)." Id.

20. The ACCC Bulletin was published in November 2001. (U.S. Ex. 6.) The Bulletin contains a Drug Index which lists Arsenic Trioxide (Trisenox) as follows.

Arsenic Trioxide (Trisenox)†	
Acute Promyelocytic Leukemia	205.00, 205.01
*Chronic Myeloid Leukemia***	205.10, 205.11
*Multiple Myeloma***	203.00 to 203.01
*Myelodysplastic Syndromes***	238.7

The Bulletin also includes a key which states: "Unless otherwise noted, drugs/indications are recognized in both compendia. Drugs marked *** have orphan drug status, and may not be reimbursed by your local carrier." The "†" symbol denotes an "FDA approved indication, not yet in

compendia" and the single star ("*") indicates that the item has been added or changed since the last issue of the Bulletin. (U.S. Ex. 6.)

21. The Bulletin also includes an "Indication Index" which lists Arsenic Trioxide under the heading "Acute Nonlymphocytic Leukemia (Erythroleukemia, Meningeal, Monocytic, Myelocytic, Myelomonocytic, Promyelocytic)" with ICD-9 Codes 205.0 to 207.0. (U.S. Ex. 6 at 15.)

The Promotion of Off-Label Uses for Trisenox

22. After the ACCC Bulletins were printed with the new Trisenox listing, Documedics sent mailings to physicians and Medicare service providers informing them that Trisenox's off-label indications were newly listed in the compendia. (U.S. Ex. 9.) The letter further states that "As per the Medicare Cancer Coverage Act of 1994, a drug listed in one of the compendia should be a covered Medicare item." Id.

23. Both Mr. Marchese and Adam Gillette of Documedics wrote early drafts of this letter. Mr. Marchese's original draft of the letter included language stating that "[Trisenox] has achieved listing [in the Compendia] through FDA approved Orphan Drug Designation" which was removed from the final version. The letter went through several revisions and was finally approved by Shawn Gilbertson of CTI and signed by Adam Gillette of Documedics. (See U.S. Exs. 19, 20, 21.) Mr. Marchese testified that his supervisors at CTI and consultants at Documedics all read the final draft of the letter and confirmed that it was factually accurate.

24. Dr. Paul Deutsche is a cardiologist employed by Empire Medical Services who received one of the Medicare notification letters from Adam Gillette on November 19, 2001. Upon receiving this letter, Dr. Deutsche verified that Trisenox's orphan drug designations had been included in the ACCC Bulletin. Dr. Deutsche did not check whether the Trisenox indications had been included in the USP-DI compendium as medically accepted but instead accepted Documedic's assertion that the indications were now reimbursable.

25. Upon this information, Dr. Deutsche decided to approve Medicare reimbursement for Trisenox prescriptions for off-label uses. (See Deutsche testimony.)

26. Dr. Deutsche sent a letter to Adam Gillette of Documedics stating, "I have confirmed that these indications [for the treatment of acute promyelocytic leukemia, multiple myeloma, myelodysplastic syndrome and chronic myeloid leukemia] are included in the compendia as noted in the ACCC Drug Bulletin." (U.S. Ex. 10.) In fact, the indications were not included in the compendia as medically accepted but were listed as having orphan drug designation in Volume III of the USP-DI.

27. CTI also sent representatives to visit oncologists, including Jay Klarnet, and told them that Trisenox was listed in the compendia for off-label uses. (See Klarnet Testimony.)

28. The Court finds that once Medicare has approved reimbursement for off-label indications, oncologists are more likely to prescribe the drug for those indications. Oncologists have an interest in ensuring that they will be paid for their services and that their patients will be able to afford the medications prescribed.

29. The Court finds that Dr. Klarnet prescribed Trisenox for off-label uses believing that a listing in the compendia meant the drug was safe and efficacious and that its cost was reimbursable by Medicare.

30. The Court finds that Dr. Klarnet would not have prescribed Trisenox for off-label uses if he had known it was not actually listed in the compendia as medically accepted. The Court also finds that Dr. Deutsche never would have approved reimbursement for those indications if he had known that they were not listed in the compendia as medically accepted.

Mr. Marchese's Involvement in the ACCC Publication

31. The Court finds that it was Mr. Marchese's idea to seek publication of Trisenox's off-label indications in the ACCC Bulletin based on Trisenox's orphan drug designations for those indications.

32. The Court finds that Mr. Marchese's interpretation of 42 U.S.C. § 1395x(t)(2)(B)(ii)(I) was genuine, though flawed. Mr. Marchese read the statute to mean that any listing in the compendia,

even if the listing only signified orphan drug status, was sufficient for Medicare reimbursement for off-label indications.

33. The Court also finds that Mr. Marchese believed publication in the ACCC Bulletin constituted compendia approval.

34. The Court finds that Mr. Marchese believed that publication in the ACCC Bulletin based on a drug's orphan drug designation was a nontraditional but legal means of being listed in the compendia.

35. The Court finds that Mr. Marchese believed that CTI was continuing its clinical trials of Trisenox and thought that the off-label indications of Trisenox would soon be eligible for FDA approval and/or compendia listing based on the results of those trials.

36. The Court finds that Mr. Marchese relied on consultants at Documedics in concluding that Trisenox's off-label indications were eligible for Medicare reimbursement because of their orphan drug status. (See R. Ex. 6.)

37. The Court also finds that Mr. Marchese believed that the off-label indications were reimbursable by Medicare because of their orphan drug designation. In an email written to Peter Sportelli after the ACCC Bulletin was published, Mr. Marchese writes:

> How pretty are those Compendia bulletins!!! By the way - in case you did not notice, I worked another little loop whole [sic]. I figured what the Hell!!! If you notice the ACCC has us listed for EVERY form of Leukemia not just AML, CML and APL. Everything from 205.00 to 207.00!!! There is a ton of stuff in there I have never even heard of. **If a state checks we will only get our Orphan Drug and USP stuff**, but my guess is that about 30-40% of the states will not check. Hey it can't hurt and man do I like working the system. I figure even if 1 state doesn't check its [sic] a bonus!!

(U.S. Ex. 7) (emphasis added). In this passage, Mr. Marchese indicates his belief that when a state checks the compendia and finds the Trisenox indications which have been granted orphan drug status, prescriptions for those indications will be reimbursed.

38. The Court finds that Mr. Marchese believed that CTI could legally promote Trisenox for its off label indications as long as it followed the provisions established by the Food and Drug

Administration Modernization Act ("FDAMA"). Mr. Marchese gave presentations to CTI management detailing what CTI must do to ensure compliance with federal regulations. (See U.S. Ex. 23.) On December 13, 2001, Mr. Marchese sent an email to Carolyn Paradise of CTI expressing his concerns that CTI's actions regarding an investigational new drug ("IND") were in violation of federal statutes. Mr. Marchese twice contacted Harold Davis at the FDA seeking clarification on the regulations Mr. Marchese feared CTI was violating. (Rel. Ex. 25, 27.) In a memo written in June 2002, Mr. Marchese included in a list of his achievements at CTI: "Submitted legal analysis to marketing and on how to promote [Trisenox] in off-label disease while complying with FDA regulations." (U.S. Ex. 11 at 2).

39. The Court finds that Mr. Marchese became concerned about the off-label promotion of Trisenox when he learned that the drug was causing patient harm and that the clinical trials had been discontinued. In December 2001, Mr. Marchese learned that CTI had discontinued its clinical trials for Trisenox's off-label indications and had no intention of completing the trials or getting medical acceptance for those indications.

40. In March 2002, Mr. Marchese learned that off-label uses of Trisenox were causing a side effect in patients called APL-like Differentiation Syndrome. Mr. Marchese also learned that CTI was no longer complying with federal regulations in its promotion of Trisenox's off-label indications. Mr. Marchese testified that while he was initially proud of getting compendia publication for Trisenox ahead of schedule, he felt that CTI had taken his achievement and "bastardized" it. The Court finds this testimony to be credible.

41. However, the Court also finds that Mr. Marchese did not act upon his concerns effectively. Although he knew of the harm being caused by off-label promotion of Trisenox, he did not act immediately to rectify CTI's legal errors. After being passed over for a promotion, Mr. Marchese wrote an angry letter to his superiors in June 2002 asking them to reconsider their decision and

listing his contributions to CTI. In that document, Mr. Marchese takes credit for the very action which he believed was causing patient harm:

> Created and implemented a 100% successful compendia submission for MDS, MM, AML, CML. **NOTE: To date the company still fails to meet ANY of the criteria set forth in compendia acceptance for all of the aforementioned disease states. Without my ability to troubleshoot and find a [sic] alternative submission route we would not have compendia in any off-label disease for a minimum of 1-3 additional years!!!**

(U.S. Ex. 11 at 2) (emphasis in original).

42. Mr. Marchese seeks credit and approval for his efforts in getting Trisenox listed in the Bulletin and is slow to blow the whistle on CTI's fraudulent actions even as he becomes aware of the harm it is causing.

43. Mr. Marchese testified that the June 2002 memo was included in a packet he sent to James Canfield of Human Resources at CTI and that the packet also included Mr. Marchese's concerns over CTI's illegal off-label promotions, kickbacks, and the harm being caused to patients. Soon after sending the packet, Mr. Marchese was suspended from his position at CTI. On July 15, 2002, Mr. Marchese received a letter from Katie Schroeder addressing Mr. Marchese's concerns. (R. Ex. 14.) Ms. Schroeder wrote:

> Some of the material appears to suggest that some of the sales force may have been promoting, or at least facilitating off-label uses. These practices do not comport with company policy and, as you are aware, policies as set forth by the Strategic Management Team and myself are the only policies of CTI.

Id. Ms. Schroeder also offered to restore Mr. Marchese to his former position as an Oncology Account Manager and instructed him to keep all concerns confidential.

Mr. Marchese's Role in Bringing an Action Against CTI

44. On July 19, 2002, Mr. Marchese returned to work at CTI.

45. On September 24, 25, and 26, 2002, Mr. Marchese attended CTI's National Sales Meeting and brought a hidden recording device with him. Mr. Marchese recorded CTI's senior management, including Katie Schroeder, making statements condoning off-label drug promotions. The recordings

also contained discussions about a sham advisory board CTI had set up to facilitate illegal kickbacks to physicians promoting Trisenox. Mr. Marchese later turned these tapes over to the government.

46. On September 27, 2002, Mr. Marchese was terminated from CTI. Upon termination, Mr. Marchese tapped into CTI's server and downloaded CTI documents onto several zip drives. He later turned these documents over to the government.

47. In October 2002 after learning that a patient had died from APL-like Differentiation Syndrome, Mr. Marchese contacted Harold Davis of the FDA who advised him to contact Dr. Joseph Grillo at the Division of Drug Marketing, Advertising, and Communications ("DDMAC").

48. From November to December 2002, Mr. Marchese contacted the Office of Inspector General three times to inform them of the health risks posed by CTI's off-label promotion of Trisenox. The Office did not respond.

49. During 2003, Mr. Marchese continued to attempt contact with Dr. Grillo and gave him a power point presentation containing documents illustrating CTI's fraudulent conduct.

50. In January of 2004, Mr. Marchese was contacted by the FBI and he met with them voluntarily. The agents questioned him about Peter Sportelli's financial activities at CTI but Mr. Marchese had no knowledge of them. At the end of the interview, Mr. Marchese asked the agents to investigate CTI's off-label promotion of Trisenox.

51. FBI Agent Rogers put Mr. Marchese in touch with the U.S. Attorney's office. On June 14, 2004, Mr. Marchese and his counsel met with Assistant United States Attorney Peter Winn, James Smith of the FDA, and several representatives from the Department of Justice to discuss the CTI fraud. At the meeting, Mr. Marchese gave the government copies of the zip drives containing CTI documents. After that meeting, the Government indicated its intention to pursue the ACCC fraud.

52. On August 2, 2004, Mr. Marchese provided AUSA Winn with more documents, including the ACCC letter from Don Jewler.

53. In August 2004 after Mr. Winn determined that the loss to the government was not sufficient to warrant pursuit of the case, Mr. Marchese informed Mr. Winn that he was not investigating the correct Medicare billing code and provided him with information about the Medicare billing codes which led Mr. Winn to locate $15.8 million in fraudulent Medicare claims.

Settlement of the Qui Tam Action

54. In September 2006, Mr. Marchese and his counsel traveled to Seattle from New Jersey to assist the government in preparing strategies to be used during mediation with CTI. CTI refused to participate in mediation if Mr. Marchese was present; instead, the Government requested that Mr. Marchese remain on-call in Seattle during the mediation process.

55. CTI and the Government settled the case for $10.5 million.

56. The Settlement Agreement does not differentiate or allocate between the three schemes brought by the government. The Agreement does not mention the particular ACCC Bulletin aspect of CTI's fraud.

Conclusions of Law

1. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C.§ 1331, 28 U.S.C. §1345, and 31 U.S.C. § 3732.

2. The False Claims Act provides that a relator shall "receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action." 31 U.S.C. § 3730(d)(1). If, however, a relator "planned and initiated" the fraud, his share may be reduced to zero percent. 31 U.S.C. § 3730(d)(3).

3. To determine the relator's share of the CTI settlement, the Court must engage in a two step analysis and Mr. Marchese and the government each bear a portion of the burden of proof.

4. First, in determining whether and how much to award the relator over the 15 percent minimum mandated by the Act, the Court should consider:

(1) the significance of the evidence provided to the government;
(2) the relator's contribution to the final outcome; and
(3) whether the government was previously aware of the information provided.

United States ex rel. Barajas v. Northrop Corp., CV 87-7288 KN, 1992 U.S. Dist. LEXIS 22817 *28 (C.D. Cal. May 14, 1992). The Court may also consider a set of criteria established by the Department of Justice which includes balancing the relator's contributions to the investigation against his own participation in the fraud. Mr. Marchese bears the burden of proving that his contribution warrants up to 25% of the settlement.

5. Second, the Government bears the burden of proving that the relator was the planner and initiator of the fraud. If the Court finds that the relator planned and initiated the fraud, it may reduce the relator's share below 15%.

6. The Court first considers Mr. Marchese's contributions to the government's case. Mr. Marchese provided the government with evidence of fraudulent activity that the government would not otherwise have discovered. The government acted on this information by bringing a Complaint against CTI involving three separate schemes. The ACCC fraud was only one of those schemes. The Settlement Agreement between the government and CTI does not differentiate between the schemes.

7. Mr. Marchese repeatedly consulted with the government on the details of the government's case and led the government to discover the bulk of the fraudulently reimbursed Medicare claims by providing AUSA Peter Winn with the correct Medicare billing code. Mr. Marchese also aided the government's mediation with CTI, providing the government with strategies to overcome CTI's defensive arguments.

8. The Court balances Mr. Marchese's contributions to the government's case against his participation in the ACCC fraud. The Court concludes that Mr. Marchese's initial interpretation of the statute governing Medicare reimbursement was honest, albeit flawed. Mr. Marchese believed

that his actions were legal in attaining publication in the ACCC Bulletin for Trisenox's off-label indications. CTI willingly adopted Mr. Marchese's interpretation of the statute and used the ACCC Bulletin to mislead oncologists. Oncologists and insurance providers were willing to accept the CTI/Documedics pronouncement that the off-label indications were reimbursable without first exercising due diligence to verify that assertion.

9. Mr. Marchese has failed to convince the Court that he acted swiftly and efficiently in bringing the case against CTI after he discovered CTI's illegal promotion of off-label indications.

10. Even after Mr. Marchese learned that CTI was violating federal regulations in its promotion of Trisenox for off-label uses, he did not immediately report the violations. Instead, he sought approval from the company, in the form of a promotion, for his efforts in having Trisenox published in the Bulletin.

11. The Court has a wide range of discretion in deciding this matter. In exercising its discretion, the Court concludes that Mr. Marchese's contributions to the case, when weighed against his own activities at CTI, warrant a 15% share of the settlement.

12. Finally, the Court does not find that Mr. Marchese was the planner and initiator of a scheme to deceive physicians into believing Trisenox was a medically accepted drug for its off-label uses and to deceive Medicare into reimbursing those off-label prescriptions. The Court concludes that Mr. Marchese relied on consultants at Documedics and his supervisors who advised that a prescription for off-label uses was eligible for Medicare reimbursement if that indication had been granted orphan drug status.

13. Because Mr. Marchese did not plan or initiate the scheme, his share of the CTI settlement cannot be reduced below fifteen percent.

Conclusion

Mr. Marchese is entitled to fifteen percent of the CTI settlement. His contributions to the government's case were significant but those contributions must be weighed against his participation

in the efforts to achieve ACCC publication for Trisenox. That publication allowed CTI to mislead oncologists and insurance providers which resulted in illegal Medicare reimbursement for Trisenox. The Court also considers Mr. Marchese's delayed protestations to the company as a factor weighing against him. Because Mr. Marchese held a reasonable belief that his actions were legal, the Court concludes that Mr. Marchese did not plan or initiate the scheme and his share will not be reduced below fifteen percent. In addition, the ACCC scheme was only part of the case brought against CTI which resulted in a recovery to the government based on information and assistance provided by Mr. Marchese.

The Clerk is directed to send copies of this order to all counsel of record.

Dated: December 14, 2007.

Marsha J. Pechman

U.S. District Judge